



OPA DATABASE GUIDE FOR PUBLIC USERS - RECERTIFICATION

**JULY 2011
VERSION 1.0**

Prepared by:
Primescape Solutions, Inc.
PRIMESCAPE
We Deliver Solutions

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CERTIFICATION

Objectives:

- Program Manager Accessing and Logging In
- Program Manager Certifying Batches
- Approving Manager Accessing and Logging In
- Approving Manager Certifying Batches

AM/PM ADVANCE NOTIFICATION	
DETAILS	EXAMPLE
<p><i>AM/PM Advance Notification</i></p> <ul style="list-style-type: none"> • Program Manager and Approving Manager receive an Advance Notification via email from OPA as a reminder of the annual recertification process. 	<p>Subject: R008-MD Advance Notification - 340B Recertification</p> <p>This is a reminder of the annual recertification process required for continued participation in the Health Resources and Services Administration's (HRSA) 340B Drug Pricing Program administered by the Office of Pharmacy Affairs (OPA).</p> <p>A link to your records will be provided via email in order to ensure your provider clinics' eligibility to continue participation in 340B, please review, update and certify information on your entities when you receive this link to your 340B records. You will only need to electronically sign one certification document after your submission of all information.</p> <p>It is extremely important that you update this data if any changes have been made. Manufacturers and distributors increasingly enforce the requirement for exact matches of information prior to providing access to 340B pricing.</p> <p>In order to avoid drug diversion and possible fraud, unfunded or non-participating entities must be decertified. Instructions on making edits and submissions are detailed at:</p> <p>http://opamet.hrsa.gov/opa/Manuals/Public User Recertification Manual.pdf</p> <p>CERTIFICATION RESPONSES ARE DUE FROM GRANTEES BY 12/31/2011. This allows time for the Office of Pharmacy Affairs to review documents prior to the quarterly database posting deadline.</p> <p>Please be advised that the 340B Program requires that all contracted or delegated provider sites (i.e., satellites and subgrantees) that purchase 340B drugs to be registered in order for patients of those sites to be eligible to receive 340B drugs. If your organization has additional or new sites, you will need to electronically submit a 340B Program Registration Form at http://opamet.hrsa.gov/opa/CERegister.aspx for each site. This activity is separate from the recertification of existing sites.</p> <p>Updates on the 340B program are regularly posted on the Office of Pharmacy Affairs website at http://www.hrsa.gov/opa.</p> <p>This annual certification is a requirement under Section 340B of the Public Health Service Act.</p> <p>Questions regarding this project may be directed to the Pharmacy Services Support Center (PSSC) Help Line by calling 202-449-9473, or by sending an email to 340B.recertification@hrsa.gov.</p>

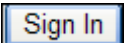
PM APPROVALS

DETAILS

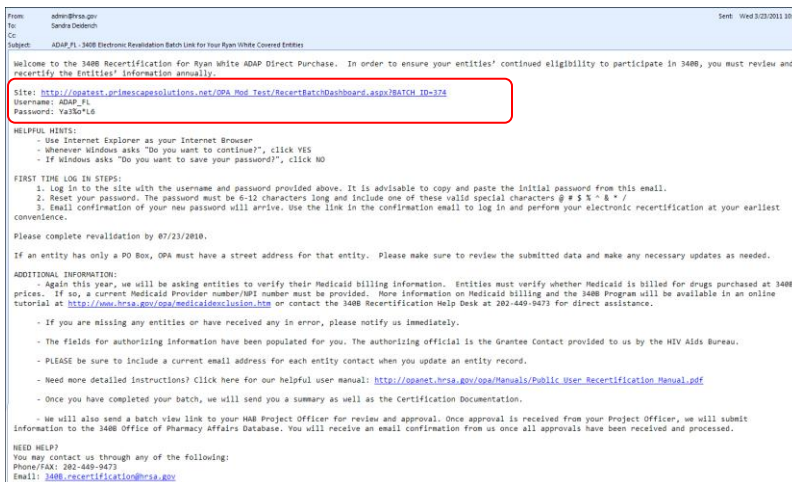
PM Electronic Revalidation Batch Notification

- PM receives email notification that a Recertification Batch is ready for certification.
- Email notification provides instructions including URL link, User Name and Password.

Program Manager Login

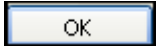
- PM can login in 340B application using the URL in the PM Login email or from **340B OPA 340B Homepage**.
 - URL link provides access to the Authentication and Authorization window opens.
- Copy and paste user name in User Name field.
 - Copy and paste password in Password field.
 - Click the  button and the U.S. Government Warning pop-up window displays.

EXAMPLE



PM APPROVALS

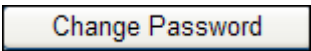
DETAILS

4. Click the  button.

5. Copy and paste password from email in Enter old password field.

6. Enter a new password.
New password must consist of the following:

- 6 to 12 characters
- 1 Uppercase letter
- 1 Special Character
@, #, %, &, *, \$, /, ^

7. Click the  button and an email acknowledgement is sent that the password is updated.



The Program Manager's User ID and Password are based on Grant Numbers and cannot be reused once all Batches in an Initiative have been reviewed and certified.

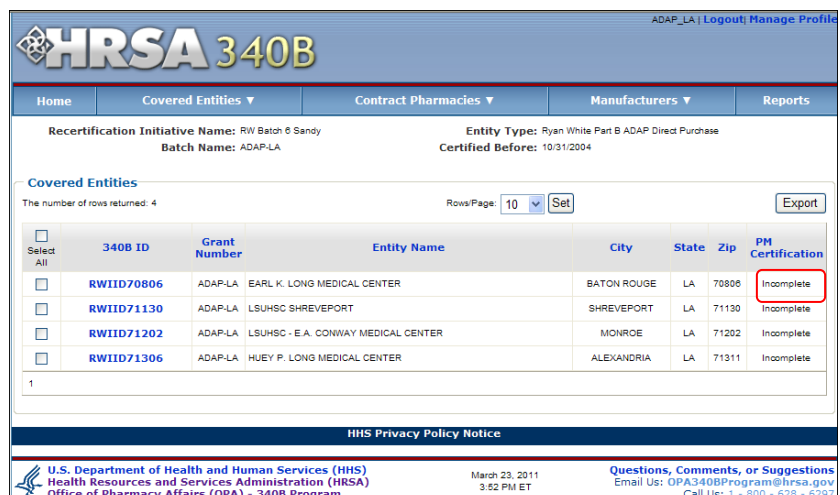
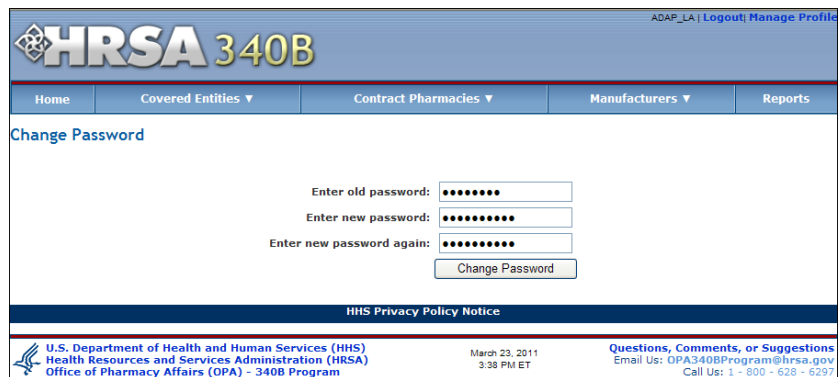
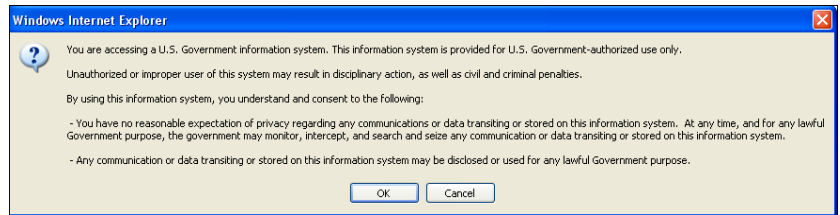
Program Manager Certifications

- PM navigates to the Batch Dashboard and the status for each CE is listed as Incomplete.
- Click on 340B ID hyperlink for each CE and the Covered Entity Detail screen displays.



PM cannot export data.

EXAMPLE



PM APPROVALS

DETAILS

- For each 340B ID, repeat same as process.
- Click **Edit** button to change information in applicable field(s).
- Click the **Certify** button to certify that CE has been certified.

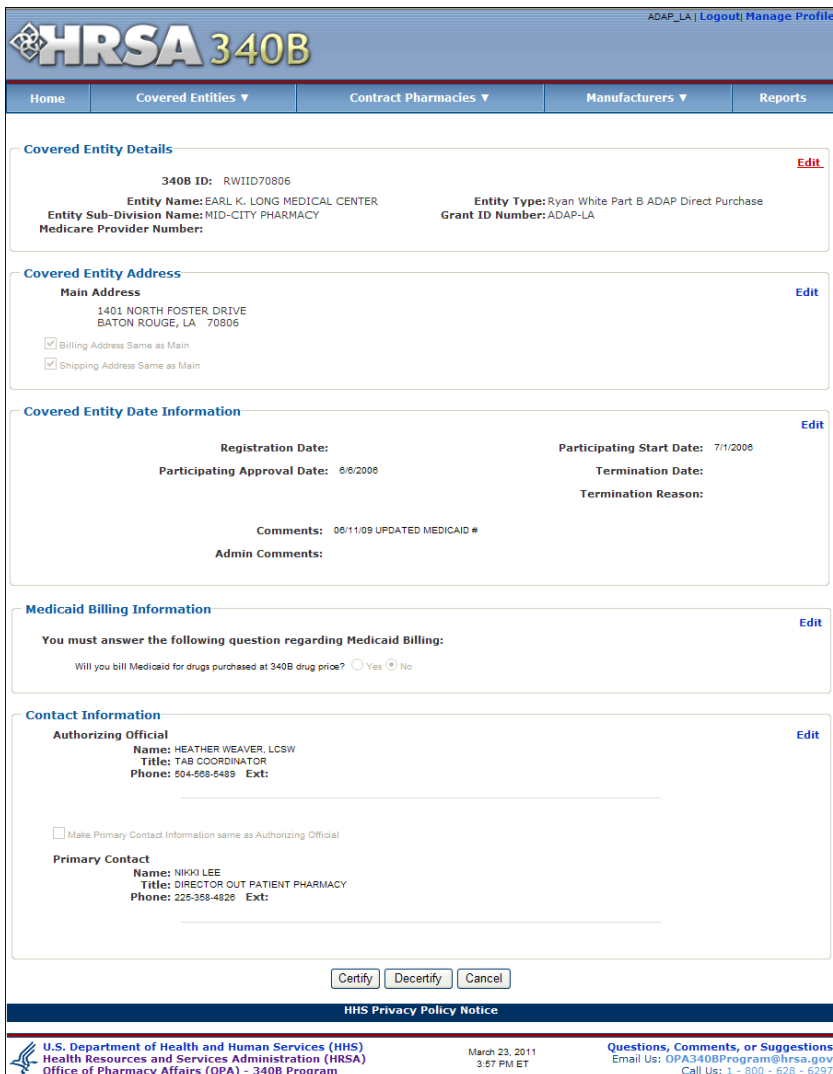
Cancel button returns to Batch Dashboard.

Decertifying

- Selecting the **Decertify** button indicates that the CE is not being certified.
- Decertifying requires:
 - Termination Date
 - Termination Reason of Decertify/Defunded

Select a Termination Reason
 340B ID# change/duplicate record
 At request of covered entity
 Site closed
 Non-response to recertification or revalidation request
 Decertified/defunded
 Failed validation
 At or below Statutorily Required DSH Percentage (CAN, DSH, PED, RRC, SCH)
 Loss of qualifying Gov't. contract (All Hospitals)
 Hospital converted to "for profit" (All Hospitals)
 Hospital type change of status (All Hospitals)
 Terminated - reason unknown
 Terminated for cause

EXAMPLE



HRSA 340B

Home Covered Entities ▼ Contract Pharmacies ▼ Manufacturers ▼ Reports

Covered Entity Details [Edit](#)

340B ID: RWIID70806
 Entity Name: EARL K. LONG MEDICAL CENTER
 Entity Sub-Division Name: MID-CITY PHARMACY
 Medicare Provider Number:
 Entity Type: Ryan White Part B ADAP Direct Purchase
 Grant ID Number: ADAP-LA

Covered Entity Address [Edit](#)

Main Address
 1401 NORTH FOSTER DRIVE
 BATON ROUGE, LA 70806
☒ Billing Address Same as Main
☒ Shipping Address Same as Main

Covered Entity Date Information [Edit](#)

Registration Date: Participating Start Date: 7/1/2008
 Participating Approval Date: 6/6/2008 Termination Date:
 Termination Reason:
 Comments: 08/11/09 UPDATED MEDICAID #
 Admin Comments:

Medicaid Billing Information [Edit](#)

You must answer the following question regarding Medicaid Billing:
 Will you bill Medicaid for drugs purchased at 340B drug price? ☐ Yes ☒ No

Contact Information [Edit](#)

Authorizing Official
 Name: HEATHER WEAVER, LCSW
 Title: TAB COORDINATOR
 Phone: 504-568-5489 Ext:
☐ Make Primary Contact Information same as Authorizing Official

Primary Contact
 Name: NIKKI LEE
 Title: DIRECTOR OUT PATIENT PHARMACY
 Phone: 225-358-4826 Ext:

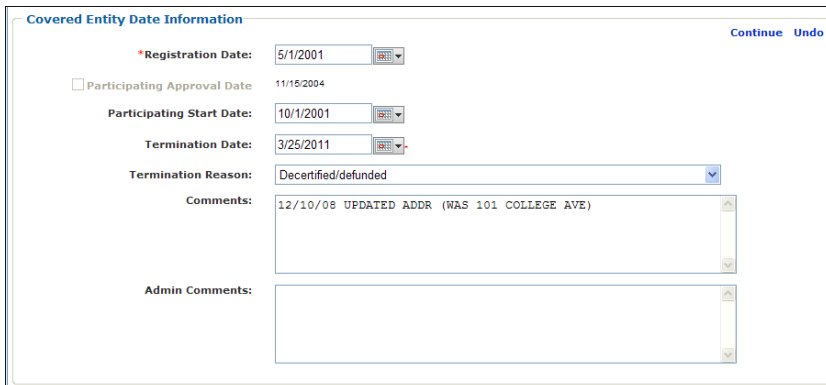
[Certify](#) [Decertify](#) [Cancel](#)

HHS Privacy Policy Notice

U.S. Department of Health and Human Services (HHS)
 Health Resources and Services Administration (HRSA)
 Office of Pharmacy Affairs (OPA) - 340B Program

March 23, 2011
 3:57 PM ET

Questions, Comments, or Suggestions
 Email Us: OPA340BProgram@hrsa.gov
 Call Us: 1 - 800 - 628 - 6297



Covered Entity Date Information [Continue](#) [Undo](#)

*Registration Date: 5/1/2001

☐ Participating Approval Date: 11/15/2004

Participating Start Date: 10/1/2001

Termination Date: 3/25/2011

Termination Reason: Decertified/defunded

Comments: 12/10/08 UPDATED ADDR (WAS 101 COLLEGE AVE)

Admin Comments:

PM APPROVALS

DETAILS

Batch Certification Completion

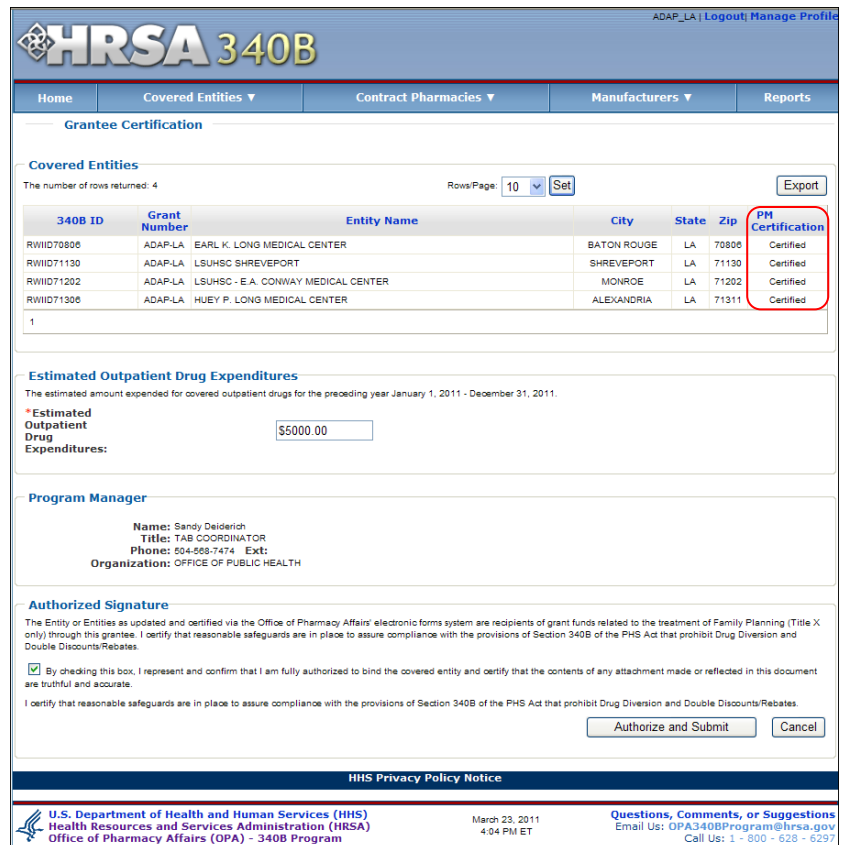
- Grantee Certification screen displays when the last CE in each batch is certified or decertified.
 - PM Certification column indicates status of CE's certification.
 - Estimated Outpatient Drug Expenditure only displays for applicable Program Types.
 - Enter dollar amount in Grantee Certification field. Include \$ sign (i.e., \$5000.00).
1. Indicate ☒ checkbox.
 2. Select **Authorize and Submit** button displays, an email notification is generated to the Approving Manager.
 3. System sends the AM login email to Approving Manager based on Entity types (FP, STD, TB, RWA, RWB Direct, RWB Rebate) if the Batch Certified by the Program Manager is the first Batch in the Initiative.



For DSH Entity Type, the AM login email step to Approving Manager is omitted since AM does not exist. Approving Manager does not exist.

- System sends an AM Notification email to the Approving Manager based on Entity types (FP, STD, TB, RWA, RWB Direct, RWB Rebate) if the Batch Certified by the Program Manager is the not the first Batch in the Initiative.

EXAMPLE



HRSA 340B

Home Covered Entities ▼ Contract Pharmacies ▼ Manufacturers ▼ Reports

Grantee Certification

Covered Entities

The number of rows returned: 4 Rows/Page: 10 Set Export

340B ID	Grant Number	Entity Name	City	State	Zip	PM Certification
RWIID70806	ADAP-LA	EARL K. LONG MEDICAL CENTER	BATON ROUGE	LA	70806	Certified
RWIID71130	ADAP-LA	LSUHSC SHREVEPORT	SHREVEPORT	LA	71130	Certified
RWIID71202	ADAP-LA	LSUHSC - E.A. CONWAY MEDICAL CENTER	MONROE	LA	71202	Certified
RWIID71306	ADAP-LA	HUEY P. LONG MEDICAL CENTER	ALEXANDRIA	LA	71311	Certified

Estimated Outpatient Drug Expenditures

The estimated amount expended for covered outpatient drugs for the preceding year January 1, 2011 - December 31, 2011.

*Estimated Outpatient Drug Expenditures: \$5000.00

Program Manager

Name: Sandy Deiderich
Title: TAB COORDINATOR
Phone: 504-568-7474 Ext:
Organization: OFFICE OF PUBLIC HEALTH

Authorized Signature

The Entity or Entities as updated and certified via the Office of Pharmacy Affairs' electronic forms system are recipients of grant funds related to the treatment of Family Planning (Title X only) through this grantee. I certify that reasonable safeguards are in place to assure compliance with the provisions of Section 340B of the PHS Act that prohibit Drug Diversion and Double Discounts/Rebates.

☒ By checking this box, I represent and confirm that I am fully authorized to bind the covered entity and certify that the contents of any attachment made or reflected in this document are truthful and accurate.

I certify that reasonable safeguards are in place to assure compliance with the provisions of Section 340B of the PHS Act that prohibit Drug Diversion and Double Discounts/Rebates.

Authorize and Submit Cancel

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Health Resources and Services Administration (HRSA)
Office of Pharmacy Affairs (OPA) - 340B Program

March 23, 2011
4:04 PM ET

Questions, Comments, or Suggestions
Email Us: OPA340BProgram@hrsa.gov
Call Us: 1 - 800 - 628 - 6297

AM APPROVALS

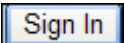
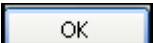
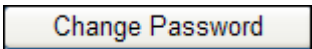
DETAILS

Approving Manager Approval

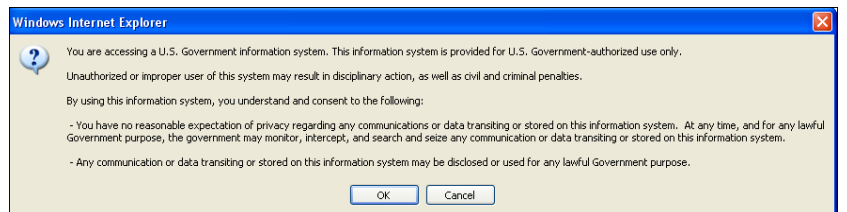
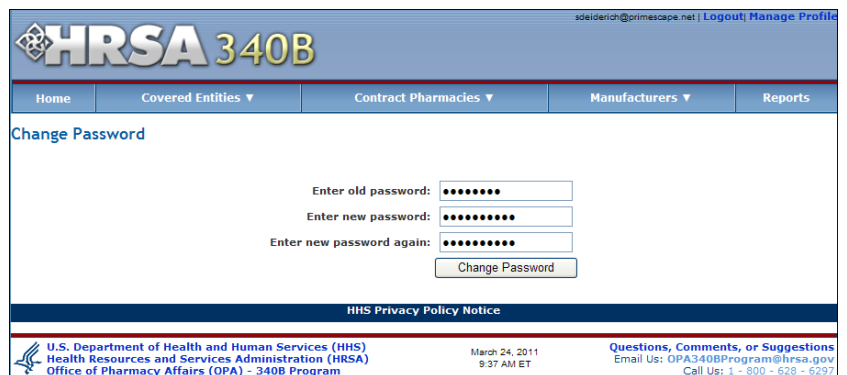
- Receives email notification.
 - Initial batch email includes the login information.
 - Subsequent emails only include batch certification notification.

Approving Manager Login

- AM logs into 340B application using the URL in the AM Login/Notification email or from **HRSA OPA 340B Homepage** URL.

1. Copy and paste user name in User Name field.
2. Copy and paste password in Password field.
3. Click the  button and the U.S. Government Warning pop-up window displays.
3. Click the  button.
4. Copy and paste password from the email in the Enter old password field. Enter new password must consist of the following:
 - 6 to 12 characters
 - 1 Uppercase letter
 - 1 Special Character @, #, %, &, *, \$, /, ^
5. Select the  button.

EXAMPLE

AM APPROVALS

DETAILS

- Receives email acknowledgement that password has been updated.



The Approving Manager's User ID and Password cannot be reused once all Batches in an Initiative have been reviewed and certified.

AM Certifications

- AM navigates to the Initiative Dashboard.
- Click on the Batch Name.



AM cannot export data.

EXAMPLE

From: Test340BDatabase@primescape.net
 To: Sandra Deiderich
 Cc:
 Subject: Authentication and Authorization Sub System - Change Password

Dear User,
 Your password has been updated in Authentication and Authorization Sub System.
 Please login using the new password in future.
 Thank You,
 Authentication and Authorization Subsystem.

HRSA 340B sdeiderich@primescape.net | Logout | Manage Profile

Home Covered Entities ▼ Contract Pharmacies ▼ Manufacturers ▼ Reports

Initiative Dashboard

Recertification Initiative Name: R/W Batch 6 Sandy
 Start Date: 3/22/2011
 End Date: 8/30/2011
 Certified Before: 10/31/2004

Program Type: Ryan White Part B ADAP Direct Purchase
 Certification Due Date: 5/28/2011
 Approval Due Date: 5/28/2011

Initiative Batches

The number of rows returned: 1 Rows/Page: 10 Set Export

Select	Batch Name	# of Entities	Certification	Approval	Approval Status
<input type="checkbox"/>	ADAP-LA	4	✓		Approve

1

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 Health Resources and Services Administration (HRSA)
 Office of Pharmacy Affairs (OPA) - 340B Program

March 24, 2011
 9:41 AM ET

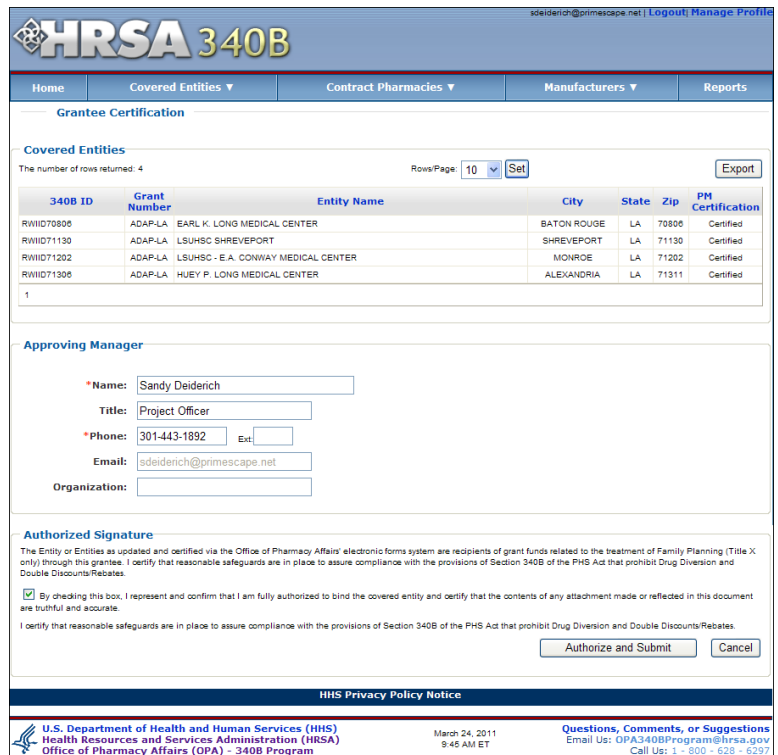
Questions, Comments, or Suggestions
 Email Us: OPA340BProgram@hrsa.gov
 Call Us: 1 - 800 - 628 - 6297

AM APPROVALS

DETAILS

3. Select the Approve link in the Approve Status column and the Grantee Certification screen displays.
4. Make edits to Approving Manager fields, if applicable.
5. Indicate ☒ checkbox.
6. Select **Authorize and Submit** button and return to the **HRSA OPA 340B Homepage**.

EXAMPLE



HRSA 340B sdeiderich@primescape.net | Logout | Manage Profile

Home Covered Entities ▼ Contract Pharmacies ▼ Manufacturers ▼ Reports

Grantee Certification

Covered Entities
The number of rows returned: 4 Rows/Page: 10 Set Export

340B ID	Grant Number	Entity Name	City	State	Zip	PM Certification
RWID70806	ADAP-LA	EARL K. LONG MEDICAL CENTER	BATON ROUGE	LA	70806	Certified
RWID71130	ADAP-LA	LSUHSC SHREVEPORT	SHREVEPORT	LA	71130	Certified
RWID71202	ADAP-LA	LSUHSC - E.A. CONWAY MEDICAL CENTER	MONROE	LA	71202	Certified
RWID71306	ADAP-LA	HUEY P. LONG MEDICAL CENTER	ALEXANDRIA	LA	71311	Certified

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Approving Manager

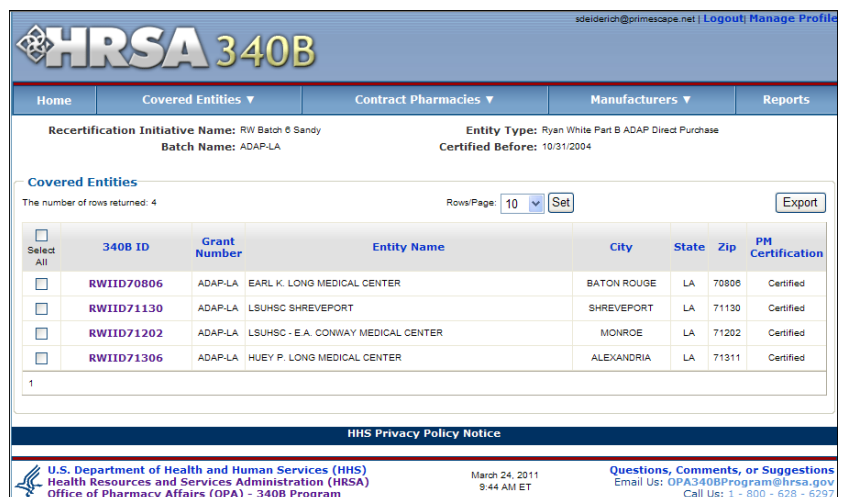
*Name:
 Title:
 *Phone: Ext.
 Email:
 Organization:

Authorized Signature
 The Entity or Entities as updated and certified via the Office of Pharmacy Affairs' electronic forms system are recipients of grant funds related to the treatment of Family Planning (Title X only) through this grantee. I certify that reasonable safeguards are in place to assure compliance with the provisions of Section 340B of the PHS Act that prohibit Drug Diversion and Double Discounts/Rebates.
☒ By checking this box, I represent and confirm that I am fully authorized to bind the covered entity and certify that the contents of any attachment made or reflected in this document are truthful and accurate.
 I certify that reasonable safeguards are in place to assure compliance with the provisions of Section 340B of the PHS Act that prohibit Drug Diversion and Double Discounts/Rebates.

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 Call Us: 1 - 800 - 628 - 6297

7. Click on 340B ID name to view a certified CE in the Batch.



HRSA 340B sdeiderich@primescape.net | Logout | Manage Profile

Home Covered Entities ▼ Contract Pharmacies ▼ Manufacturers ▼ Reports

Recertification Initiative Name: RW Batch 6 Sandy **Entity Type:** Ryan White Part B ADAP Direct Purchase
Batch Name: ADAP-LA **Certified Before:** 10/31/2004

Covered Entities
The number of rows returned: 4 Rows/Page: 10 Set Export

Select All	340B ID	Grant Number	Entity Name	City	State	Zip	PM Certification
<input type="checkbox"/>	RWID70806	ADAP-LA	EARL K. LONG MEDICAL CENTER	BATON ROUGE	LA	70806	Certified
<input type="checkbox"/>	RWID71130	ADAP-LA	LSUHSC SHREVEPORT	SHREVEPORT	LA	71130	Certified
<input type="checkbox"/>	RWID71202	ADAP-LA	LSUHSC - E.A. CONWAY MEDICAL CENTER	MONROE	LA	71202	Certified
<input type="checkbox"/>	RWID71306	ADAP-LA	HUEY P. LONG MEDICAL CENTER	ALEXANDRIA	LA	71311	Certified

1

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AM/PM CERTIFICATION COMPLETION	
DETAILS	EXAMPLE
<p><i>AM/PM Certification Completion</i></p> <ul style="list-style-type: none"> AM and PM receive email notification when a Batch is reviewed and approved by OPA. 	<p>Thank you for completing the 2011 recertification of your 340B participating providers and clinics. No further action is required on your part at this time.</p> <p>You may now review your entities' information at this link - http://opatest.primescapesolutions.net/OPA_Mod_Test/CESearch.aspx.</p> <p>If you find any errors, please let us know as soon as possible.</p> <p>NEED HELP OR HAVE ADDITIONAL QUESTIONS? You may contact the 340B Recertification Team through any of the following: Phone: 202-449-9473 Email: 340B.recertification@hrsa.gov</p>